

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1 – 5, 7 – 20, 23 – 36, and 47 – 52 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1 – 5, 7 – 20, 23 – 36, and 47 – 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baudino et al. (USPN 6,353,762) in view of Brehm (USPN 5,067,495).

Regarding **claims 1, 4, 19, 20, 22, 24, and 36**, Baudino discloses a method of affecting chronic pain, comprising: implanting a stimulator in a target site of the brain of a patient with chronic pain (e.g. column 9, lines 61 – 66); providing a stimulation signal to the stimulator to stimulate the target site and adjusting the stimulation signal if necessary (e.g. column 9, lines 35 – 37); wherein the target site is the anterior limb of the internal capsule (e.g. column 9, line 66), the anterior nucleus of the thalamus (e.g. column 9, line 67), the dorsomedial nucleus of the thalamus (e.g. column 9, line 67), the lateral hypothalamus (e.g. column 10, line 3), and/or the ventral pallidum (e.g. column 9, line 65). Brehm teaches it is known to determine a patient's threshold for pain at a first time, provide a stimulation signal for treating chronic pain, determine the patient's threshold for pain at a second time (e.g. column 4, lines 11 – 15), and adjust the stimulation signal if necessary in response to the determination of the patient's threshold for pain at the second time in order to affect the chronic pain (e.g. column 4, lines 15 – 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the closed loop method of treating chronic pain as taught by Baudino with determining the patient's threshold for pain and adjusting the stimulation signal if necessary as taught by Brehm, since such a modification would provide the predictable results of maximizing the stimulation signal to a point of optimal therapy without additional painful sensations.

Regarding **claims 2, 3, 5, 7 - 18, 21, 23, and 25 - 35**, Baudino in view of Brehm discloses the claimed invention, but fails to expressly teach that the target area is selected from the groups consisting of: the insular cortex, the secondary somatosensory

Art Unit: 3762

cortex, the inferior frontal gyrus, the middle frontal gyrus, the superior frontal gyrus, the medial frontal gyrus, the parahippocampal gyrus, the precuneus, the mammillary body, and the tectum. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the cortical stimulation and the deep brain stimulation as disclosed by Baudino in view of Brehm with the stimulation of the identified cortical or deep brain sites, because Applicant has not disclosed that the stimulation of the claimed sites provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the stimulation of the anterior limb of the internal capsule or the anterior nucleus of the thalamus as taught by John in view of Baudino, because it provides the predictable results of effective stimulation to affect chronic pain.

Therefore, it would have been an obvious matter of design choice to modify John in view of Baudino to obtain the invention as specified in the claim(s).

In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cortical and deep brain stimulation methods as taught by Baudino in view of Brehm and try different cortical and/or deep brain stimulation sites, such as the stimulation of the claimed sites, since it was known in the art that cortical and deep brain stimulation systems and methods use stimulation of the insular cortex, the secondary somatosensory cortex, the inferior frontal gyrus, the middle frontal gyrus, the superior frontal gyrus, the medial frontal gyrus, the parahippocampal gyrus, the precuneus, the mammillary body, or the tectum and since it would be obvious to one having ordinary skill in the art to try different cortical or deep

Art Unit: 3762

brain stimulation sites to provide the predictable results of determining the correct cortical or deep brain region to stimulate to affect chronic pain since different brainstem stimulation sites provide activation of selective nerves and different body regions having different functions and would allow the physician to choose the most effective site to modulate body function.

Regarding **claims 47, 48, 50 and 51**, Baudino discloses a closed loop method of treating chronic pain, as previously mentioned. Brehm teaches it is known to determine a patient's threshold for pain comprising a tactile stimulus (e.g. column 5, lines 15 – 20) and/or a noxious stimulus (e.g. 68 in Fig. 2; any stimulation that would require the therapy to be changed would indicate a negative outcome and, thus, be a noxious stimulus). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the closed loop method of treating chronic pain as taught by Baudino with determining the patient's threshold for pain comprising tactile and/or noxious stimuli as taught by Brehm, since such a modification would provide the predictable results of maximizing the stimulation signal to a point of optimal therapy without additional painful sensations.

Regarding **claims 49 and 52**, Baudino in view of Brehm discloses determining the patient's threshold for pain, as previously mentioned. Examiner has taken official notice that it is well known to stimulate a target site by increasing or decreasing the temperature. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the determining the patient's threshold for pain as taught by Baudino in view of Brehm with an increase or decrease in temperature as

Art Unit: 3762

is known in the art, since such a modification would provide the predictable results of optimizing the therapy to quickly and efficiently affect the chronic pain.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. John (USPN 6,066,163) discloses determining an increase or decrease in temperature (e.g. column 13, lines 52 – 55).

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH M. DIETRICH whose telephone number is (571)270-1895. The examiner can normally be reached on M-F, 8:00 - 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on 571-272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. D./
Examiner, Art Unit 3762

/Scott Getzow/
Primary Examiner, Art Unit 3762